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INTERVENTIVE-DIAGNOSTIC DEVICE

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INTERVENTIVE-DIAGNOSTIC DEVICE

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אינטרקיור בע״מ

INTERVENTIVE-DIAGNOSTIC DEVICE

FIELD OF THE INVENTION

The present invention relates generally to medical devices, and specifically to treatment and diagnostic devices providing feedback to a user of the device concerning one or more of the user's physiological variables.

BACKGROUND OF THE INVENTION

Devices which measure a physiological variable of a user and which then provide feedback to the user for the purpose of modifying the variable are well known in the art. U. S. Patent 5,076,281, and U. S. Patent 5,800,337, to the present inventor, which are incorporated herein by reference, both describe methods and devices for modifying biorhythmic activity by measuring one or more variables of a user. The patents describe the generation of a stimulus which is provided to the user, so as to change the biorhythmic activity of the user is a way that is related to the monitored biorhythmic activity.

U. S. Patent 5,423,328, to the present inventor, which is also incorporated herein by reference, describes a stress-detecting device for monitoring respiration, and, in particular, a method for detecting and monitoring circumferential changes in the chest or abdomen of a user resulting from breathing. U. S. Patent 4,580,574, to the present inventor, which is also incorporated herein by reference, describes a method for non-invasively monitoring properties of living tissue.

Devices which are at least partially operated remotely are also known in the art. U. S. Patent 4,102,332, to Gessman, which is incorporated herein by reference, describes a device for remote telephonic resuscitation. The device includes an electrocardiograph and a defibrillator which are carried by a

user with a known history of cardiac symptoms, and which may be used to diagnose and treat acute cardiac symptoms. In order to facilitate the diagnosis and treatment, the device may be connected to a telephone line, so that a remote physician may make the diagnosis and perform the treatment.

U. S. Patent 5,782,878, to Morgan, which is incorporated herein by reference, describes a system including an external defibrillator, a defibrillator communicator, and a communication network. In order to perform a defibrillation, information is transmitted back and forth between a patient and a communication station.

U. S. Patent 5,794,615, to Estes, which is incorporated herein by reference, describes a system for treatment of congestive heart failure. The patent describes controlling the flow rate of a pressurized gas delivered to a patient during the two phases of the respiratory cycle independently. The system may be fully automated responsive to feedback provided by a flow sensor that determines the estimated patient flow rate.

U. S. Patent 5,678,571, to Brown, which is incorporated herein by reference, describes a method for treating a medical condition in a patient comprising choosing a psychological strategy for treating the medical condition, and then encoding electronic instructions for an interactive video game. The game implements the psychological strategy, and loads the electronic instructions into a microprocessor-based unit equipped with a display for displaying the video game. The game contains scoring instructions to quantitatively analyze the medical condition of the patient, counseling instructions and self-care instructions. The video game can be used in conjunction with a physiological variable measuring device connected to the microprocessor-based unit.

U. S. Patent 5,752,509, to Lachmann, et al. describes a system for artificially ventilating a patient. The ventilation system has a gas delivery unit for delivering controllable inspiration pulses to a patient, a monitoring unit for measuring at least one parameter related to the function of the circulatory system, such as a blood gas analyzer, and a control unit for determining an optimal peak inspiratory pressure and pressure amplitude for the inspiration pulse, based on the measured circulatory system parameter.

SUMMARY OF THE INVENTION

It is an object of some aspects of the present invention to provide methods and apparatus which enable a user to improve a physiological variable of the user.

It is a further object of some aspects of the present invention to provide methods and apparatus which convey a stimulus to a user so as to improve a physiological variable of the user.

It is yet a further object of some aspects of the present invention to provide remotely-mediated methods and apparatus which enable a user to improve a physiological variable of the user.

It is an additional object of some aspects of the present invention to provide remotely-mediated methods and apparatus which enable a user to modify physiological variables to improve health or manage a specific disease.

In preferred embodiments of the present invention, an interventive-diagnostic system comprises a local computing device at a local site, which applies an intervention to a user at the site and receives one or more input signals from one or more sensors attached to the user. The input signals are indicative of a physiological condition of the user. The local device makes a preliminary analysis of the input signals, thereby generating a set of analyzed data, and typically modifies a subsequent intervention responsive to the analyzed data. The set of analyzed data and/or some or all of the input signals are transmitted as data to a remote facility for further analysis. The remote facility comprises a program operator, optionally using a computer. The program operator makes a further analysis of the data received, and transmits a result of the analysis back to the local device and/or to the user. The local device uses the result from the remote

facility and the input signals to modify a subsequent intervention which is applied to the user.

Preferably, the input signals and the analysis thereof made by the local device are stored by the device in a data logger, typically comprising an electronic memory and/or a permanent storage medium. Some or all of the contents of the data logger are preferably transmitted intermittently, on-line, to the remote facility for processing. Typically, the stored data are utilized in combination with the input signals to generate the preliminary analysis. Additionally, by examining data stored in the data logger from several sessions, trends can be calculated by the device or at the remote facility to evaluate the success of a particular intervention strategy. Subsequently, either on-line or off-line, the intervention strategy may be changed responsive to the evaluation.

Typically, the further analysis performed by the program operator comprises activities which would be difficult or impossible to perform at the local site. The result of the analysis may comprise a direct response to the user, or a communication between computing devices. For example, the program operator may provide help to the user for operating the local device. Alternatively, the program operator and/or the computer at the remote facility may transmit the result directly to the local device, for example, in order to change a characteristic, setting or operational mode of the device. For some applications, a human program operator is not necessary, and the computer at the remote facility automatically performs the analysis.

An "intervention" is to be understood in the disclosure and in the claims as a generation of a stimulus intended to modify one or more physiological variables of a user. For example, the intervention transmitted to the user may comprise

an intelligible input stimulus, such as a sound pattern and/or dynamic graphical pattern, which is generated according to one or more predefined programs resident within the local device. The stimulus is typically intended to modify breathing of the user, for example, by training the user to initiate a new breathing pattern. Most preferably, the intervention is one which is known to have a positive effect on aspects of one or more of the user's physiological systems, such as the cardiovascular, pulmonary, and/or neurological systems.

The local device and/or the remote facility are also able to generate a "diagnosis" responsive to a physiological variable of the user. A diagnosis is to be understood in the disclosure and in the claims as the generation of an evaluation responsive to one or more physiological variables of the user, which evaluation may be monitored without modifying the physiological variables.

The combination of a local device and a remote facility operating together to provide intervention and diagnosis significantly enhances the ability of the local device to generate an intervention which benefits the user. Furthermore, the combination enables the remote facility to follow effects, such as changes in diagnosis, generated by the intervention and to interact with the local device and/or the user in order to give appropriate further feedback as appropriate.

Wellness and disease-management programs are one of the goals of modern healthcare systems. These are addressed in preferred embodiments of the present invention, in which the interventive-diagnostic system is operated over an extended period of time, on the order of months, and progress of the user is followed by the remote facility during the period. Most preferably, a plurality of programs are stored within the local computing device, which programs comprise a sequence of modes of device operation which are followed by the user

during the period. During the extended period, the remote facility monitors that the user is correctly adhering to a particular program, provides help as appropriate, and obtains data relating to the user's progress.

In some preferred embodiments of the present invention, the stimulus provided to the user is in the form of a game, and the parameters of the game are altered so that playing the game induces the user to modify the physiological variable. Having a stimulus in the form of a game, most preferably an audiovisual game, encourages users who are children to actively participate in a therapeutic intervention process. For example, children with pulmonary or motor-related neurological disease, such as asthma or hyperactivity, may be benefited by use of these embodiments of the invention.

In some preferred embodiments of the present invention, the local device is provided to the user from the remote facility, or from some other facility, for an evaluation period, during which period the user operates the system as described above. On completion of the evaluation period, the user is able to return the device to one of the facilities, or continue to use the device after a payment has been received by one of the facilities. Alternatively or additionally, the local device is given at no charge to a receiver, and is enabled to exchange data with the remote operator, as described hereinabove, responsive to regular payments to the remote facility.

There is therefore provided, in accordance with a preferred embodiment of the present invention, a method for inducing a modification of a physiological variable of a user, including:

applying an intervention via a device to the user responsive to a set of one or more intervention parameters;

measuring a physiological variable responsive to the intervention;

transmitting a signal responsive to the physiological variable to a remote facility for processing;

receiving a reply from the remote facility responsive to the signal; and

applying the intervention via the device to the user responsive to the reply.

Preferably, the physiological variable is a variable representative of a biorhythmic activity of the user, and is changed as a direct consequence of the intervention. Further preferably, the intervention includes instructing the user to voluntarily change the physiological variable, directly or indirectly, for example, by modifying a parameter of the user's breathing, or by affecting blood flow responsive to respiration and/or respiratory movements.

Preferably, transmitting the signal includes connecting the device to the remote facility via a distributed network or via a direct communication link.

In a preferred embodiment, the device and the remote facility include respective industry-standard computers, operating respective programs.

Preferably, applying the intervention includes providing an intelligible sensory stimulus to the user.

Further preferably, transmitting the signal and receiving the reply include communicating a verbal message or transmitting and/or receiving a set of data.

Still further preferably, the device includes a comparator which compares a current physiological state of the user to a previous physiological state of the user, in order to determine a change in the physiological state responsive to the intervention.

Still further preferably, measuring the physiological variable includes generating a diagnosis and modifying the set of one or more intervention parameters responsive to the diagnosis.

In a preferred embodiment, the intervention includes a routine intervention, applied to the user at generally regular intervals, for example, in a non-emergency setting.

There is also provided, in accordance with a preferred embodiment of the present invention, a method for inducing a modification of a physiological variable of a user, including:

providing an electronic game having a game parameter, the game to be played by the user;

applying an intervention via the game to the user responsive to the game parameter;

measuring a physiological variable responsive to the intervention; and

modifying the game parameter responsive to the measured physiological variable.

Preferably, providing the electronic game includes:

connecting the game to a remote facility;

transmitting the game parameter to the remote facility, and

transmitting the physiological variable to the remote facility.

In a preferred embodiment, connecting the game to the remote facility includes receiving a response from the remote facility for the purpose of modifying the game parameter. Alternatively or additionally, another user operates the method at the remote facility.

Preferably, the physiological variable is changed as an indirect consequence of the intervention. In a preferred embodiment, the physiological variable includes an indication

of blood oxygenation, cardiac electrical state, respiration or blood pressure.

In a preferred embodiment, the user has congestive heart failure, asthma, chronic obstructive pulmonary disease, hypertension, or cystic fibrosis. Alternatively, the user is generally healthy, and uses aspects of the present invention in order to obtain psychological stress-relief and/or relaxation, or for purposes of muscle re-education, athletic training, or entertainment. For some applications, measuring the physiological variable includes receiving a sound responsive to respiratory activity, such as wheezing.

Alternatively or additionally, measuring the physiological variable includes receiving an indication of microvascular blood flow and/or of the stiffness of at least one blood vessel.

There is further provided, in accordance with a preferred embodiment of the present invention, a method for modifying a physiological variable of a user, including:

providing the user with an interventional device capable of modifying the variable responsive to an input from a remote facility;

enabling the device to operate during a time-limited period; and

enabling the device to operate after the time-limited period, responsive to a receipt of payment.

Preferably, providing the user with the interventional device includes facilitating the user and the remote facility to enter into an agreement regarding operation of the device. Typically, the receipt of payment includes a transfer of funds to the remote facility.

There is still further provided, in accordance with a preferred embodiment of the present invention, a method for enabling an intervention, including:

receiving a signal corresponding to a measured physiological variable of a remote user, the physiological variable having been measured responsive to a first intervention via a device; and

transmitting a reply responsive to the signal, to modify aspects of a second intervention applied via the device.

Preferably, receiving the signal includes generating a diagnosis responsive to the measured physiological variable of the remote user.

There is additionally provided, in accordance with a preferred embodiment of the present invention, apparatus for inducing a modification of a physiological variable of a user, including:

a sensor, which generates a measure of the physiological variable of the user;

a stimulation unit, which provides an intervention to the user; and

a device, which is coupled to the sensor and the stimulation unit, and which:

determines a set of one or more intervention parameters responsive to the measure of the physiological variable;

operates the stimulation unit responsive to the set of one or more intervention parameters;

transmits a signal responsive to the physiological variable to a remote facility for processing;

receives a reply from the remote facility responsive to the signal; and

applies the intervention via the stimulation unit to the user responsive to the reply.

Preferably, the device includes a comparator and a memory, wherein an indication of a physiological state of the user is intermittently stored in the memory, and wherein the comparator compares a current indication of the physiological state to a previous indication of the physiological state, in order to determine a change in the user's physiological state.

In a preferred embodiment, the stimulation unit includes an industry-standard computer.

There is yet additionally provided, in accordance with a preferred embodiment of the present invention, apparatus for inducing a modification of a physiological variable of a user, including:

an electronic game to be played by the user, the game applying an intervention to the user responsive to a game parameter;

a sensor, which measures a physiological variable responsive to playing of the game; and

a processor which modifies the game parameter responsive to the measured physiological variable.

Preferably, the processor is located at a remote facility. In a preferred embodiment, another user plays a similar game at the remote facility.

There is also provided, in accordance with a preferred embodiment of the present invention, apparatus for enabling an intervention, including:

a receiver, located at a local facility, which receives a signal corresponding to a measured physiological variable of a remote user, the physiological variable having been measured responsive to a first intervention via a device; and

a transmitter, located at the local facility, which transmits a reply responsive to the signal, to modify aspects of a subsequent intervention applied via the device.

The present invention will be more fully understood from the following detailed description of the preferred embodiments thereof, taken together with the drawings, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic illustration of an interventive-diagnostic system, according to a preferred embodiment of the present invention;

Fig. 2 is a schematic block diagram of inputs to a local computing device of the interventive-diagnostic system of Fig. 1, according to a preferred embodiment of the present invention;

Fig. 3 is a schematic block diagram showing the local computing device of the interventive-diagnostic system of Fig. 1, according to a preferred embodiment of the present invention;

Fig. 4 is a flow chart of a comparator of the local computing device, according to a preferred embodiment of the present invention;

Fig. 5 is a schematic diagram illustrating a number of possible configurations of the interventive-diagnostic system of Fig. 1, according to a preferred embodiment of the present invention;

Fig. 6 is a schematic block diagram showing a number of possible modes in which the local computing device is able to operate, according to a preferred embodiment of the present invention;

Fig. 7 is a schematic illustration showing how the interventive-diagnostic system of Fig. 1 is applied to a congestive heart failure patient, according to a preferred embodiment of the present invention;

Fig. 8 is a schematic flow chart showing steps involved in a rehabilitation program for the patient described with reference to Fig. 7, according to a preferred embodiment of the present invention;

Fig. 9 is a schematic illustration showing how the interventive-diagnostic system of Fig. 1 is applied to an asthmatic child, according to a preferred embodiment of the present invention;

Fig. 10 is a schematic flow chart giving steps involved in a game program to enhance breathing self-control under psychological stressors, for the child described with reference to Fig. 9, according to a preferred embodiment of the present invention;

Fig. 11 is a schematic flow chart giving steps involved in a blood pressure treatment program, according to a preferred embodiment of the present invention; and

Fig. 12 is a schematic flow chart giving steps involved in a process of providing the interventive-diagnostic system of Fig. 1 to a user, according to a preferred embodiment of the present invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Fig. 1 is a schematic illustration of an interventive-diagnostic system 20, according to a preferred embodiment of the present invention. System 20 comprises a local computing device 26, which receives signal data from sensors 23, 24 and 25 coupled to a user 22 at a local site 21. Typically, at least some of the signal data represents biorhythmic activity of user 22. The signal data comprise signals from one or more health status sensors 23, one or more biorhythmic-activity sensors 24 and/or one or more benefit-related sensors 25. Local device 26, the sensors, and the signal data received by the local device are described in greater detail hereinbelow. The connection between local device 26 and sensors 24 and 25 may be wired or wireless.

Local device 26 performs a first analysis on the received signals to generate a set of analyzed data, which is transferred to a remote facility 28, such as a hospital or medical clinic. A program operator 32 and a computer 34, controlled by operator 32, are preferably located at the facility. Remote facility 28 is physically distant from local device 26 and user 22. Preferably, remote facility 28 communicates with local device 26 via a distributed network 36 such as the Internet. Alternatively or additionally, program operator 32 and/or computer 34 communicate with local device 26 and/or user 22 by other means known in the art, for example by a telephone modem or by voice, using a telephone.

Operator 32 and/or computer 34 preferably further analyze the data set received from local device 26, generating a result which is transmitted to local site 21 and preferably saved in a memory 38 of computer 34. For example, the result from remote facility 28 may be verbal help to enable user 22 to modify operation of device 26, or the remote result may be data communication to the local device. Local device 26

utilizes the result from the remote facility, and/or the set of analyzed data, and/or the signals received from sensors 24 and 25, to generate an intervention which is provided to user 22 via a stimulation unit 30. The intervention typically comprises an intelligible sensory input stimulus, such as a sound pattern provided through earphones worn by user 22, a dynamic graphic pattern provided on a screen visible to the user, or a regularly repeating audio and/or visual pattern, such as a metronome. The stimulus preferably changes at least one aspect of the biorhythmic activity of user 22.

Fig. 2 is a schematic block diagram of categories of variables which are typically input as signals or data to local device 26, according to a preferred embodiment of the present invention. A first category, herein termed biorhythmic-activity variables, comprises signals generated by a biorhythmic activity of user 22, wherein the biorhythmic activity is one which may be modified by the user. For example, biorhythmic activity variables may be signals generated by an appropriate sensor in response to the breathing of user 22, or in response to eye-blinking, or in response to flexure and/or rigidity of one or more voluntary or semi-voluntary muscles of the user. Biorhythmic-activity signals are measured by one or more appropriate biorhythmic-activity sensors, such as a force transducer for monitoring breathing movements via changes in chest or abdominal circumference, based on a strain-gauge which is attached to an elastic belt, such as that described by Gavish in the above-cited U. S. Patent 5,423,328. Preferably, the one or more biorhythmic-activity sensors are self-installed by user 22.

A second category of variables, herein termed benefit-related variables, comprises signals generated by measurements of physiological variables of user 22, wherein the variables cannot normally be modified by the user at will. Typically,

benefit-related variables include parameters of the user that are altered by a pathology or other phenomenon of user 22 which is being treated by device 26. For example, benefit-related variables may be those corresponding to blood pressure, blood oxygenation (e.g., SpO2), pulse-wave velocity, variations in skin blood volume (e.g., as measured by photoplethysmography), respiration parameters (e.g., peak air flow), or an electrocardiogram (ECG) measurement of user 22. Benefit-related variables are measured by one or more appropriate benefit-related sensors, such as a sphygmomanometer, a pulse oximeter, or an electrocardiograph, which are preferably self-installed by user 22. Alternatively, the one or more benefit-related sensors are installed by someone other than user 22, such as a parent, if user 22 is a child. Additionally, benefit-related variables may be monitored continuously or at specific time points, such as when measuring blood pressure by a standard sphygmomanometer.

A third category of variables, herein termed health status variables, comprise data which give details of the general state of user 22. For example, health status variables typically comprise weight, height, age, resting respiration rate, and resting heart rate of user 22, as well as the user's ECG and blood pressure, measured during an intervention session. As appropriate, device 26 evaluates the health status variables to determine whether they are within safe ranges. For example, for a user having a specified gender, age, and weight, a certain measured heart rate may be determined to be too high or too low, and thus force a premature termination of the intervention and an alarm signal.

Preferably, some of the health status variables are input to local device 26 via a keyboard which may be coupled to or integrated with device 26. Alternatively or additionally, health status variables may be input to device 26 by

connecting the device to a computer. Furthermore health status variables may be input to device 26 by an appropriate sensor, such as an electronic weigh-scale, when the variable to be input is weight. Storage and evaluation of changes of the health status variables can be used to determine a trend in the user's medical condition, as described hereinbelow.

Fig. 3 is a schematic block diagram showing components of local device 26, according to a preferred embodiment of the present invention. Generally, local device 26 generates intervention parameters responsive to input signals, and provides a stimulus via stimulation unit 30 to user 22, responsive to the intervention parameters. Local device 26 is preferably implemented in discrete components or a combination of discrete and custom or semi-custom components. Alternatively, device 26 is implemented by operating a program on an industry-standard computer coupled to a display monitor.

Device 26 comprises a central processing unit (CPU) 52, which is coupled to and controls the operation of the individual components of device 26 described hereinbelow. For clarity, lines are not shown between CPU 52 and the other components. It will be appreciated that there are many ways within the scope of the present invention to achieve objects of the invention, and the particular components and methods described with respect to Fig. 2 are an example of these. A biorhythmic activity detector 64 receives a biorhythmic-activity signal, herein designated BAS, from sensor 24, and generates an output responsive to BAS, representing one or more pattern components of the sensed biorhythmic activity of the user. Pattern components and other relevant concepts for implementing detector 64 are described in the above-cited U. S. Patent 5,076,281 and U. S. Patent 5,800,337. Preferably, the output of detector 64 includes intervention parameters, herein termed biorhythm activity parameters (BAP), which are

of a quantitative nature. A benefit related detector 62 receives a benefit-related signal, herein designated BRS, from sensor 25, and generates an output responsive to BRS representing one or more pattern components of the sensed benefit-related signals of the user. Preferably, the output of detector 62 includes intervention parameters, herein termed benefit-related parameters (BRP), which are of a quantitative nature.

A health status detector 60 receives health status data, herein designated HSD, by methods described above, and generates an output responsive to the HSD representing one or more components of the health status of the user. Preferably, the output of detector 60 includes current values relating to one or more physiological variables that may be altered by application of embodiments of the present invention. These values are herein termed health status parameters (HSP), and are typically of a quantitative nature. Intervention parameters BAP, BRP, and HSP most preferably comprise specific time-point analyses of their respective signals, which are used to identify special points characterizing the signals' structures, such as maxima, minima, and turning points (e.g., as described by Gavish in U. S. Patent 5,800,337). A further set of parameters, herein termed cross-correlation parameters (CCP), are derived by correlating BAS, BRS, and HSP signals, so as generate a cross-correlation and a cross-spectral analysis of the signals. Most preferably, values of BAS, BAP, BRS, BRP, HSS, HSP, and CCP are stored in a data logger/memory 54, which preferably comprises industry-standard volatile and non-volatile memory components.

A comparator 50 receives values of BAP, BRP, HSP, and CCP in order to compare the values against values which have been previously stored in data logger 54. The operation of comparator 50 is described in detail hereinbelow, with

reference to Fig. 4. If the values of BAP, BRP, HSP, and CCP are within predefined limits, comparator 50 enables a driver 46, whose function is to operate a biorhythmic activity modifier 44. Preferably, driver 46 operates by providing a set of operational command inputs to modifier 44 so as to cause a component of the stimulus input to the user to be related to a component of the existing biorhythmic activity of user 22 which is sensed by one or more of sensors 23, 24, and/or 25. Comparator 50 is also able to activate an alarm generator 58, in the event that one or more of the health status parameters and/or benefit-related parameters are outside a predefined range.

A mode storage component 55 stores a plurality of modes under which device 26 is able to operate, which modes are described in greater detail below with respect to Fig. 6. A sequencer 56 interacts with mode storage 55 so as to choose a sequence of modes which is to be utilized by driver 46 in operating biorhythmic activity modifier 44. Both mode storage 55 and sequencer 56 are addressable by remote facility 28, most preferably by interfacing with CPU 52 (as described above for device 26, with reference to Fig. 1), so that sequences of operational modes may be updated. Operational mode sequences may be modified for a number of reasons, for example, to optimize a particular therapeutic strategy, to abandon a strategy that is not producing desired results, or simply to keep user 22 interested. A display 66, most preferably an industry-standard alphanumeric display, displays to user 22 data corresponding to signals and parameters described hereinabove, as well as other data such as help signals, according to commands received from CPU 52.

Biorhythmic activity modifier 44 receives parameters BAP and BRP, respectively from detectors 64 and 62 and/or from driver 46, and provides user 22 with a stimulus input which is

able to change at least one aspect of the user's biorhythmic activity. For example, the stimulus input provided to user 22 may be a sound pattern, which varies over time to teach user 22 to alter a time period associated with inhaling and/or exhaling.

In some applications, program operator 32 and/or computer 34 interact with components of local device 26, other than as described above, so as to be able to follow and vary the operation of device 26. Program operator 32 and/or computer 34 are able to read data from, and write data to, data logger/memory 54, and also to overwrite any of the data stored in data logger/memory 54. Preferably, threshold values determined at remote facility 28 are supplied to comparator 50, which are used by the comparator to perform comparisons described hereinbelow, and which are herein termed criteria via threshold (CRT) values.

Fig. 4 is a flow chart showing operation of comparator 50, according to a preferred embodiment of the present invention. Typically, health status parameters HSP are compared with CRT values which are input to a health range decider. If the values are outside the health range delineated by the CRT values, alarm generator 58 is triggered, driver 46 is disabled, and a signal announcing the out-of-range state is sent to data logger 54. If parameters HSP are within range, they are used, together with previous HSP parameters from data logger 54, in order to calculate an updated HSP trend. The new trend is checked to see if it is within acceptable limits, using HSP trend criteria derived from the CRT values. If the HSP trend is in within acceptable limits, driver 46 is enabled. If the HSP trend is not within acceptable limits, driver 46 is disabled. The trend of a parameter may be evaluated by analyzing repeated measurements thereof over a prescribed period. Preferably, the analysis comprises a

statistical analysis, such as calculating a regression to determine a slope and to know the statistical significance of the determined slope. Alternatively or additionally, other curve-fitting methods known in the art may be used.

Benefit-related parameters BRP are used, together with previous BRP parameters from data logger 54, in order to calculate an updated BRP trend. The new trend is checked to see if it is within an acceptable range, using BRP trend criteria derived from the CRT values. If the BRP trend is within the acceptable range, no further action is taken by device 26. Otherwise, a signal announcing the out-of-range state is sent to data logger 54, and a driving strategy selector is informed. The driving strategy selector determines which parameters of driver 46 are to be modified, to what degree, and in what manner. In order to make its determination, the selector also receives an analysis of the performance of user 22. The analysis is performed by comparing the BAP parameters with the BRP parameters generated by detector 62, and may be responsive to inputs from remote facility 28.

Fig. 5 is a schematic diagram illustrating a number of possible configurations of system 20, according to a preferred embodiment of the present invention. In a first configuration, user 22 is coupled to device 26 as described hereinabove with reference to Fig. 1. While user 22 is operating device 26, the user contacts remote facility 28 and relays the data displayed by display 66 to program operator 32. Most preferably, user 22 contacts operator 32 by telephone, and verbally relates the data shown on the display. Program operator 32 analyzes the relayed data, and verbally informs user 22 of the results of the analysis, whereupon, depending on the results, user 22 may be instructed to make adjustments to device 26. It will be appreciated that a configuration such as that illustrated is

especially useful when device 26 is operated by user 22 as a generally self-contained unit, wherein user 22 requires help and/or instruction in operating the device and modifying parameters thereof.

In a second configuration, user 22 sets device 26 to communicate directly with computer 34 in remote facility 28, during an intervention session, or following one or more sessions. User 22 contacts program operator 32, preferably via telephone, to inform the operator that device 26 is connected, whereupon the operator is able to download and inspect data from components of device 26, such as data in data logger 54. Alternatively or additionally, program operator 32 is able to alter settings of device 26, for example, by uploading new music or new values of CRT parameters to the device, and is also able to communicate verbally with user 22. This configuration is useful when device 26 is to be checked and/or updated by operator 32 on an intermittent basis. The configuration is also useful for enabling program operator 32 to inform user 22 of his progress, based on data stored in device 26.

In a third configuration, device 26 preferably comprises a local industry-standard personal computer coupled to a display monitor, as described hereinabove with respect to Fig. 3. One or more of sensors 23, 24 and/or 25 are coupled to the local computer. The local computer communicates with computer 34 at remote facility 28, preferably via network 36, so that, for example, a new audiovisual multimedia output is able to be transmitted from the remote facility to the local computer. In addition, program operator 32 is able to communicate with user 22, for example by telephone as described above, and/or by an industry-standard network communication program installed on the local computer and on computer 34, such as a chat program. This configuration is useful when full two-way continuous

communication between remote facility 28, user 22, and device 26 is required. In this configuration, for example, messages, data reports, and verbal and non-verbal information may be exchanged.

Fig. 6 is a schematic block diagram showing a number of possible operational modes of local device 26, according to a preferred embodiment of the present invention. Most preferably, mode storage component 55 holds parameters corresponding to the modes described hereinbelow. In an intervention mode, device 26 generates a stimulus for user 22, with the intention of modifying a variable of user 22. In a diagnostic mode, device 26 performs one or more measurements of a variable of user 22, without modifying the variable. In a diagnostic-interventive mode, device 26 initiates an intervention and performs a diagnosis, or repeatedly cycles between diagnosis and intervention in any desired pattern. In a testing mode, device 26 executes a programmed sequence of interventions and/or diagnoses, in order to characterize physiological variables of user 22. Most preferably, sequencer 56 stores a plurality of programmed sequences. In a hold mode, device 26 is placed into a waiting state until activated by an action of user 22 or remote facility 28.

Examples of modes which typically are applicable to users with congestive heart failure, although the modes may also be applied to other users, are described in Table I hereinbelow. A notation which may be used to characterize the mode is also given in the table.

TABLE I

Mode	Notation	Description
Intervention 1	I1(RR)	Slow down breathing pattern using a musical pattern stimulus. The pattern is implemented interactively, at a breathing rate (RR breaths per minute) set by a predetermined algorithm.
Intervention 2	I2(RR,T)	Entrain breathing at a rate of RR breaths per minute, for a period of T minutes.
Diagnosis 1	D1(C)	Measure and record parameters based on breathing. When C = 1, record signals and parameters in data logger 54. When C = 0, record only parameters in the data logger.
Diagnosis 2	D2(C)	Measure and record parameters based on breathing and pulse oximetry.
Diagnostic-Interventive 1	DI1	Perform D1(1) followed by I1, so as to measure long-term benefit parameters, and then perform a therapeutic intervention.
Testing 1	T1	A sequence [D2, I2(15,2), I2(10,2), I2(16,2), D2] measures acute response to intervention, to characterize parameters of the cardiovascular control system.

Examples of modes which typically are applicable to users who are asthmatic children, although the modes may be applied to other users, are described in Table II hereinbelow.

TABLE II

Mode	Notation	Description
Intervention 3	I3	Present scenes including a psychological stressor, e.g., in the context of a video game.
Intervention 4	I4	Present "neutral" scenes, without a psychological stressor.
Diagnosis 3	D3	Measure and record breathing-related parameters.
Testing 2	T2(1)	Perform a sequence [D3, I1(1), D3] to measure acute response to the intervention, and to characterize physiological variables which are sensitive to the stressor.

Fig. 7 is a schematic illustration showing system 20 applied to a congestive heart failure patient, according to a preferred embodiment of the present invention. Sensor 24 preferably comprises a force transducer/respiration sensor 70 (such as the force transducer described hereinabove with reference to Fig. 2), coupled to a belt placed around the chest of user 22, who is a congestive heart failure patient. Sensor 25 comprises a pulse oximeter 71, which is placed on a finger of user 22. Such sensors, and their method of application and use, are well known in the art. Stimulation unit 30 preferably comprises a set of earphones 72 worn by user 22, which provide a music-like pattern according to outputs from biorhythmic activity modifier 44. Alternatively or additionally, unit 30 comprises an external speaker, for example, the loudspeaker of a personal computer. Device 26

uses input signals from sensor 70 to generate biorhythmic activity parameters corresponding to a respiration rate, an inspiration time, an expiration time, and a desired graded performance of user 22. Device 26 also makes measurements of benefit-related parameters derived from pattern classification statistics, such as a percentage of time spent in a pathological breathing state, oxygen saturation levels and their fluctuations, and heart rate.

Fig. 8 is a schematic flow chart showing steps involved in a rehabilitation program for the patient described with reference to Fig. 7, according to a preferred embodiment of the present invention. Preferably, remote facility 28 and user 22 operate in configuration 1, as described hereinabove. In an introduction step, operator 32 introduces user 22 to device 26 and the program described hereinbelow. Operator 32 also determines appropriate patient characteristics, from data logger 54, and then transmits initial setup parameters to device 26. Finally, operator 32 instructs user 22 to operate device 26 between 6 AM and 10 AM each day, during the course of the program.

In a "set baseline" step, user 22 fills in a questionnaire, to provide details of currently-prescribed medications, lifestyle, etc. to remote facility 28. Subsequently, user 22 uses device 26 during ten days of measurements, in which signals and parameters are recorded, corresponding to D2(1) of Table I. After completion of the ten days of measurements, user 22 performs an acute-response test corresponding to T1 of Table I. Device 26 then moves to hold mode until activated by operator 32.

In an initial analysis step, data stored in data logger 54 are transmitted to remote facility 28, where operator 32 reads and analyzes the data. Operator 32 then transfers

appropriate parameters CRT to device 26, to enable regular operation of the device.

In a first operation step, user 22 operates device 26 in diagnostic-interventive mode DI1 for one week, after which device 26 moves to hold mode. User 22 transmits data stored in data logger 54 to remote facility 28. Most preferably, the data is transmitted according to configuration 2, described hereinabove. Alternatively, user 22 may contact operator 32 and transmit the data in one of the alternative configurations described above. After the data have been transmitted to operator 32, device 26 returns from hold to its normal working mode.

In a second operation step, user 22 and operator 32 repeat the initial analysis step and the first operation step for four weeks. At the completion of this step, user 22 performs acute-response test T1 described in Table I. User 22 also fills in a second questionnaire.

In a third operation step, user 22 and operator 32 repeat the initial analysis step and the first operation step for between two and four months, while operator 32 checks the data and modifies operation of device 26 as described above.

In a completion step, user 22 completes both questionnaires, and is invited to remote facility 28 to discuss the results of the program.

Fig. 9 is a schematic illustration showing how aspects of system 20 are applied in the form of a computer game for user 22, in this case an asthmatic child, according to a preferred embodiment of the present invention. Preferably, the application is for the purpose of enhancing self-control of user 22's breathing when exposed to psychological stressors. Optionally, wheezing is monitored as a benefit-related variable. Alternatively or additionally, respiratory efforts

are increased by user 22 by breathing through a resistive load, in order to strengthen and orchestrate the activity of respiratory muscles.

Most preferably, device 26 is implemented in a computer 74 comprising an audiovisual monitor 76, as described hereinabove. Respiration sensor 70, described above with reference to Fig. 7, is coupled to a belt placed around the chest of user 22. Sensor 70 is preferably coupled directly to computer 74, for the purpose of monitoring wheezing as a benefit-related variable. Typically, wheezing is detected by mounting a small microphone (not shown) near user 22's throat. Computer 74 and user 22 are preferably, but not necessarily, in communication with remote facility 28, as described above with reference to configuration 3, so that operator 32 is able to present a dynamic audio-visual pattern, e.g., a game, as a sensory stimulus to user 22. Computer 74 uses input signals from sensor 70 to generate biorhythmic activity parameters corresponding to a respiration rate, an inspiration time, an expiration time, and a graded performance of user 22. Most preferably, the graded performance quantitatively characterizes the breathing of user 22, and comprises, for example, a percentage of time during a session spent executing a prescribed breathing procedure, or other prescribed intervention.

Device 26 also makes measurements of benefit-related parameters derived from pattern classification statistics, respiration rate, inspiration time, and expiration time. Such benefit-related parameters include, for example, a percentage of time spent in a pathological breathing pattern. Device 26 also makes measurements of health status parameters derived from the respiration rate of user 22.

Fig. 10 is a schematic flow chart showing steps of a game program to enhance breathing self-control during exposure to

psychological stressors, for the child described with reference to Fig. 9, according to a preferred embodiment of the present invention. In an introduction step, operator 32 communicates with user 22 and explains rules to be followed during the course of the game program, for example, how to mount sensor 70 correctly. Preferably, the explanations comprise audiovisual explanations and/or questions and answers via an electronic communications program, such as a chat program. The introduction step concludes by user 22 demonstrating to operator 32 that the user is able to correctly mount sensor 70 and operate device 26.

In a "learn control" step, user 22 is given a short course in how to control her/his breathing, typically by slowing down breathing using intervention mode I1, as described above in Table I. Preferably, the stimulus presented to user 22 is in the form of a moving picture on monitor 76, such as an object whose activity responds to the user, and, to encourage proper breathing, can only enter a "high-score" region of the screen when the user's breathing profile closely matches a desired profile. Alternatively or additionally, the size or content of an oxygen bottle carried by an on-screen spaceman, varies in apparent volume or other characteristics responsive to the breathing profile. As described hereinabove, the actual variation of the stimulus is controlled by the output of biorhythmic modifier 44. Preferably, the course includes compiling for user 22 a score representative of how well the course has been followed.

In an evaluation step, diagnosis mode D3, described above in Table II, is applied to user 22, and the results are evaluated by operator 32. At the conclusion of the evaluation, operator 32 transmits parameters CRT to computer 74 so as to alter parameters of the game responsive to the evaluation of the operator.

In an altered game step, user 22 plays the game under the altered conditions. Most preferably, the altered conditions include one or more "adventure" sessions, and one or more "break" sessions. An adventure session typically comprises an intervention mode wherein a psychological stressor is applied, for example I(3) described in Table II. The stressor may be, for some applications, the tension induced in the user by the game's difficulty. A break session comprises an intervention mode wherein no psychological stressor is applied, for example intervention mode I4 described in Table II. During the course of the altered game step, sensitivity to the stressor is measured, e.g., by testing mode T2(1), and the results of the test are used to alter the structure of the game. For example, the percentage of adventure sessions may be increased and the percentage of break sessions may be correspondingly decreased. User 22 most preferably receives scores giving an evaluation of the user's performance during the course of the altered game step.

The game continues by repeating the evaluation step and the altered game step, the repetition being made conditional on user 22 achieving a specific score in the altered game step. Most preferably, each repetition increases the level of difficulty of the game, e.g., by increasing the percentage of time spent in adventure sessions.

In some preferred embodiments of the present invention, a plurality of games, which are similar to the game described with reference to Fig. 10, are operated by a corresponding plurality of users. Most preferably, the users are in communication with each other via network 36, so that respective scores of the users are visible to some or all of the users. Most preferably, operator 32 is also able to see the plurality of scores of the users. Friendly competition or

team-work between the users may be encouraged, for the benefit of all.

In some preferred embodiments of the present invention, the game as described with reference to Fig. 10 is operated by user 22 without the intervention of operator 32, optionally under the supervision of an adult. In these embodiments, the functions of operator 32 may alternatively be performed by device 26, whereby a mode and a sequence of program steps are stored respectively in mode storage component 55 and sequencer 56.

It will be understood that whereas preferred embodiments of the present invention have been described generally with respect to a user having a pathology, it is within the scope of the present invention for the user to be generally healthy, and to choose to use aspects of the present invention in order to obtain psychological stress-relief and/or relaxation, or for purposes of muscle re-education, athletic training, or entertainment.

Fig. 11 is a schematic flow chart showing steps involved in a blood pressure treatment program, according to a preferred embodiment of the present invention. An objective of the program is to reduce the blood pressure of user 22 within a period of about 6 weeks. Most preferably, system 20 is set up as described above with reference to Fig. 9, so that user 22 is connected to device 26 and respiration sensor 70. Alternatively, device 26 is implemented as a stand-alone device. Further alternatively, other sensors may additionally be used, such as a photoplethysmography (PPG) sensor, an ECG sensor, or a blood pressure monitor. Depending on the sensors used, benefit-related parameters comprising rate and stability of breathing, state of small blood vessels, heart rate variability, values of pulse wave velocity, and blood pressure are utilized in performing the program. Health status

variables used in the program typically comprise blood pressure, heart rate and heart rate variability, and breathing pattern.

In an introduction step, user 22 receives device 26 and appropriate sensors. Operator 32, who is most preferably a physician, introduces user 22 to the program, and provides user 22 with instructions as to how to operate device 26 and the sensors. This step may take place at remote facility 28, or partly at the remote facility and partly at site 21.

In an initiation step, user 22 performs self-training, after which, measurements are made to determine the user's baseline characteristics. At the end of the baseline characterization, user 22 performs various tests. Operator 32 accesses device 26 to download the data generated by the program to date, and analyzes the data. The results of the analysis are then used by operator 32 to set up device 26, for example, including appropriate parameters and a choice of music to be stored in the mode storage component of device 26.

In a main program step, user 22 treats himself for an extended period of time, for example 4 weeks. During this time operator 32 monitors data generated by the treatment. In case of difficulty, operator 32 and user 22 are able to communicate with each other, for example, to provide help to user 22 in performing the treatment. This step is repeated as needed, and during the course of the step, operator 32 modifies the setup of device 26 according to the progress of user 22.

Fig. 12 is a schematic flow chart showing steps involved in a process of providing system 20 to user 22, according to a preferred embodiment of the present invention. Device 26 and one or more of sensors 24 and 25 are provided to user 22 from remote facility 28, or from another facility remote from local site 21, so that user 22 is able to transport the device and sensors to the local site, such as the user's home.

Alternatively, device 26 is provided to user 22 as a program which can be installed in a computer operated by the user at local site 21. Most preferably, when device 26 and/or the sensors are provided to user 22, the user enters into an agreement with remote facility 28 or with the other remote facility, so as to be able to fully implement interventive-diagnostic system 20, as described hereinabove. Preferably, the agreement provides for user 22 to receive services from remote facility 28, which services comprise facility 28 operating system 20 for an evaluation period without user 22 paying for the services. In the event that user 22 wishes to continue the services after the evaluation period, the user, an insurance company, or another entity pays for the services, for example on a monthly basis. In the event that user 22 does not wish to continue to receive the services, the program is terminated.

It will be understood that it is within the scope of the present invention for an intervention, as described hereinabove, to include use of physical apparatus not specifically mentioned. This apparatus may comprise, for example, substantially any anaerobic or aerobic recreational or therapeutic exercise equipment known in the art. Alternatively or additionally, the apparatus may comprise an airway resistance-generation device, such as a Positive End Expiratory Pressure (PEEP) valve, an inspiratory or expiratory breathing retrainer, or other respiration-manipulation unit. Alternatively, the intervention may be partially or completely free of apparatus, and involve, for example, 15 minutes of walking, pursed-lips breathing, a Valsalva maneuver or aerobic exercise in time-relation with breathing movements (e.g., as applied in Qi-gong), or intentionally-generated breathing patterns, as done in Yoga and zan-zen. In some of these applications, principles of the present invention may be utilized in combination with a medical device already in use

by the user, such as a ventilator. The principles may be applied, for example, to wean the user from the ventilator.

It will be appreciated that the individual preferred embodiments described above are cited by way of example, and that specific applications of the present invention may employ only a portion of the features described hereinabove, or a combination of features described with reference to a plurality of the figures. The full scope of the invention is limited only by the claims.

CLAIMS

1. Apparatus for facilitating improving health of a user, comprising:

a first sensor, adapted to measure a first physiological variable, which is indicative of a voluntary action of the user, and to generate a first sensor signal responsive thereto;

a second sensor, adapted to measure a second physiological variable, which is not entirely under the direct voluntary control of the user, and to generate a second sensor signal responsive thereto; and

circuitry, adapted (a) to receive, at a first time, the first and second sensor signals, and, responsive thereto, to generate a first output signal which directs the user to modify a parameter of the voluntary action, and (b) to receive, at a second time after the user has modified the parameter of the voluntary action, the first and second sensor signals, and responsive thereto, to generate a second output signal which directs the user to further modify the parameter of the voluntary action.

2. Apparatus according to claim 1, wherein the circuitry is adapted to generate the first and second output signals such that if the user modifies a parameter of the voluntary action responsive to the first and second output signals, then the second physiological variable will be changed in a desired manner.

3. Apparatus according to claim 1, wherein the circuitry is adapted to generate the first and second output signals to direct the user to modify the parameter of the voluntary action, so as to facilitate an improvement in congestive heart failure of the user.

4. Apparatus according to claim 1, wherein the circuitry is adapted to generate the first and second output signals to direct the user to modify the parameter of the voluntary action, so as to facilitate treatment of a blood pressure disorder of the user.

5. Apparatus according to claim 1, wherein the circuitry is adapted to generate the first and second output signals to direct the user to modify the parameter of the voluntary action, so as to facilitate an improvement in asthma of the user.

6. Apparatus according to claim 1, wherein the circuitry is adapted to generate the first and second output signals to direct the user to modify the parameter of the voluntary action, so as to facilitate an improvement in cystic fibrosis of the user.

7. Apparatus according to claim 1, wherein the circuitry is adapted to generate the first and second output signals to direct the user to modify the parameter of the

voluntary action, so as to facilitate weaning the user from a mechanical ventilator.

8. Apparatus according to claim 1, wherein the circuitry is adapted to generate the first and second output signals to direct the user to modify the parameter of the voluntary action, so as to facilitate an increase of heart rate variability of the user.

9. Apparatus according to claim 1, and comprising a speaker, wherein the circuitry is adapted to drive the speaker to output natural sounds, so as to direct the user to modify the parameter of the voluntary action.

10. Apparatus according to claim 1, and comprising a screen, wherein the circuitry is adapted to drive the screen to display one or more respective patterns corresponding to the first and second output signals, so as to direct the user to modify the parameter of the voluntary action.

11. Apparatus according to claim 1, wherein the second sensor comprises a blood pressure sensor.

12. Apparatus according to claim 1, wherein the second sensor comprises a photoplethysmographic sensor.

13. Apparatus according to claim 1, wherein the second sensor comprises a blood oximeter.

14. Apparatus according to claim 1, wherein the second sensor comprises an electrocardiographic sensor.

15. Apparatus according to claim 1, wherein the second sensor comprises an electroencephalographic sensor.

16. Apparatus according to claim 1, wherein the second sensor is adapted to measure the second physiological variable so as to facilitate a determination of pulse wave velocity of blood in blood vessels of the user.

17. Apparatus according to claim 1, wherein the first sensor comprises a respiration sensor.

18. Apparatus according to claim 17, and comprising a belt adapted to be placed around a torso of the user, wherein the respiration sensor is adapted to generate the first sensor signal responsive to a change in circumference of the torso.

19. Apparatus according to claim 1, wherein the second sensor comprises a pulse oximeter.

For the Applicnt,

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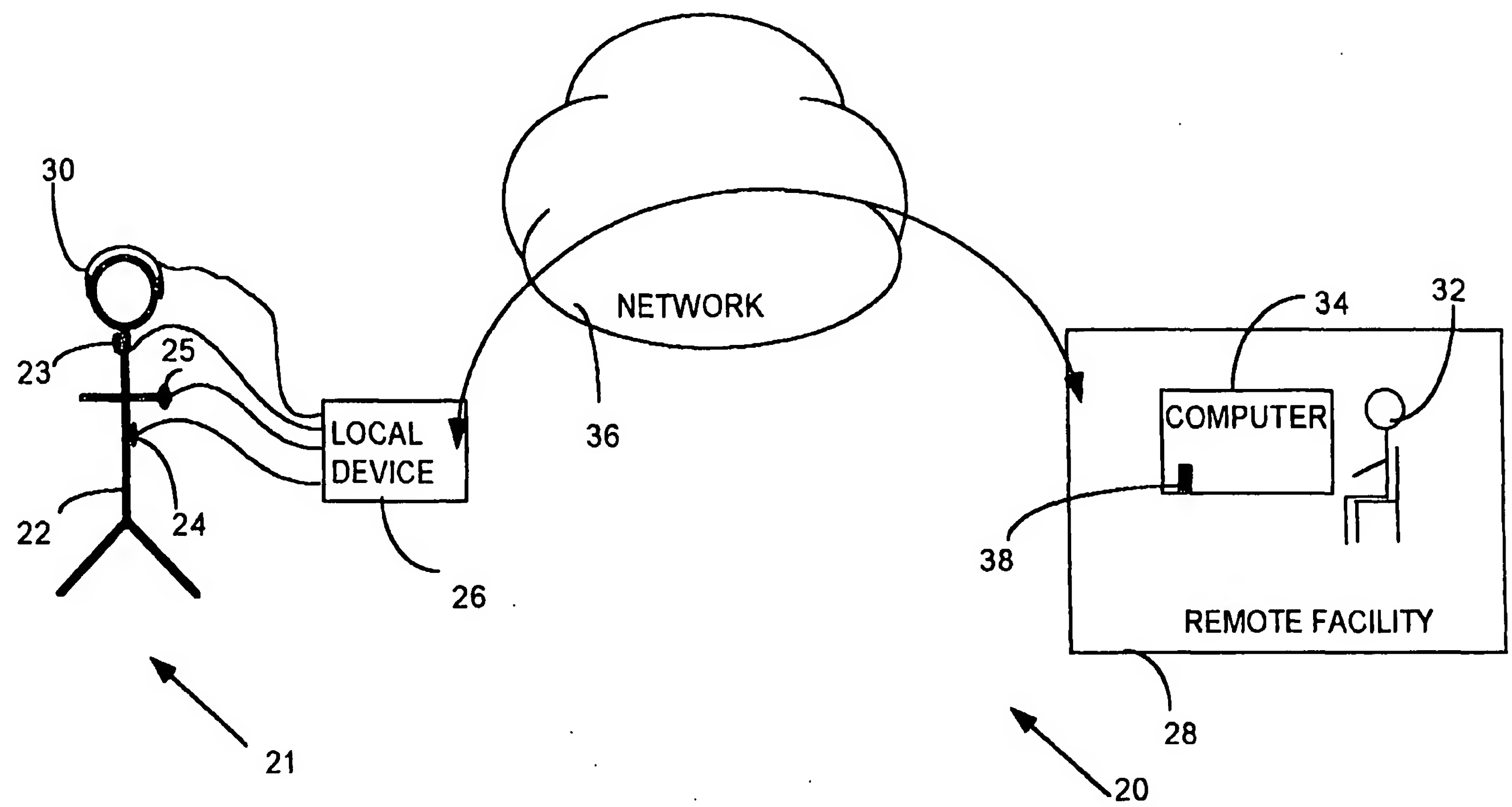

30
23
25
22
24
LOCAL DEVICE
26
21
NETWORK
36
34
32
COMPUTER
38
REMOTE FACILITY
28
20

FIG. 1

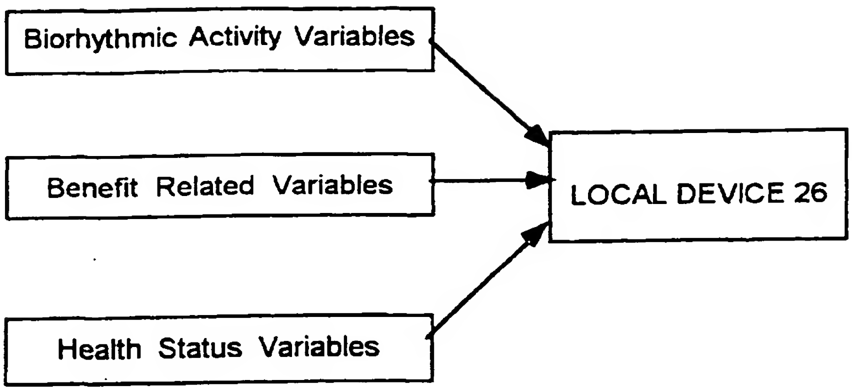
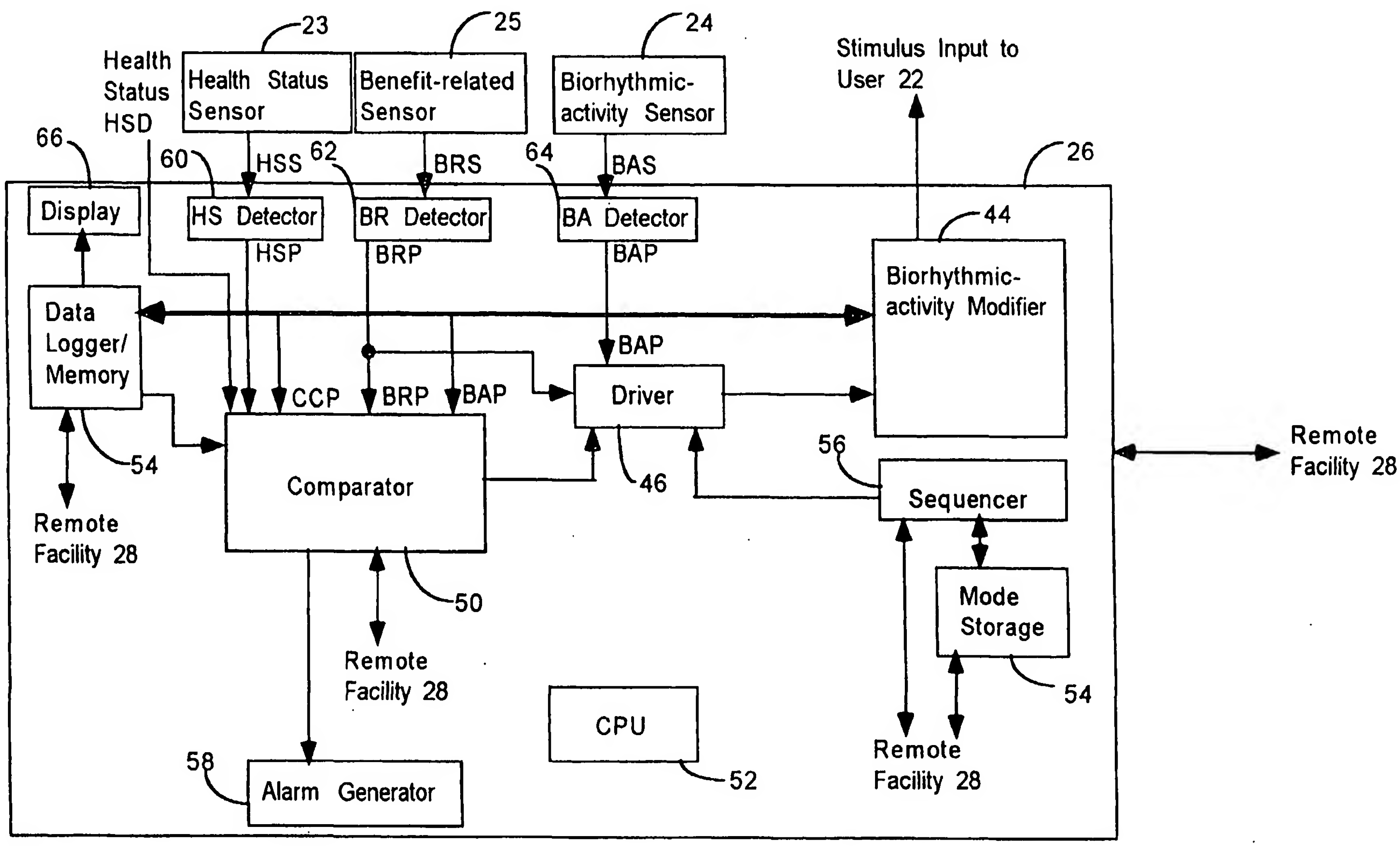

Biorhythmic Activity Variables
Benefit Related Variables
Health Status Variables
LOCAL DEVICE 26

FIG. 2



Health Status HSD
Health Status Sensor
23
Benefit-related Sensor
25
Biorhythmic-activity Sensor
24
Stimulus Input to User 22
26
66
60
HSS
62
BRS
64
BAS
Display
HS Detector
BR Detector
BA Detector
HSP
BRP
BAP
44
Biorhythmic-activity Modifier
Data Logger/ Memory
BAP
CCP
BRP
BAP
Driver
54
Remote Facility 28
Comparator
46
56
Sequencer
Remote Facility 28
50
Remote Facility 28
Mode Storage
54
CPU
52
Remote Facility 28
58
Alarm Generator

FIG. 3

NINE SHEETS SHEET NO. 4
130818/2

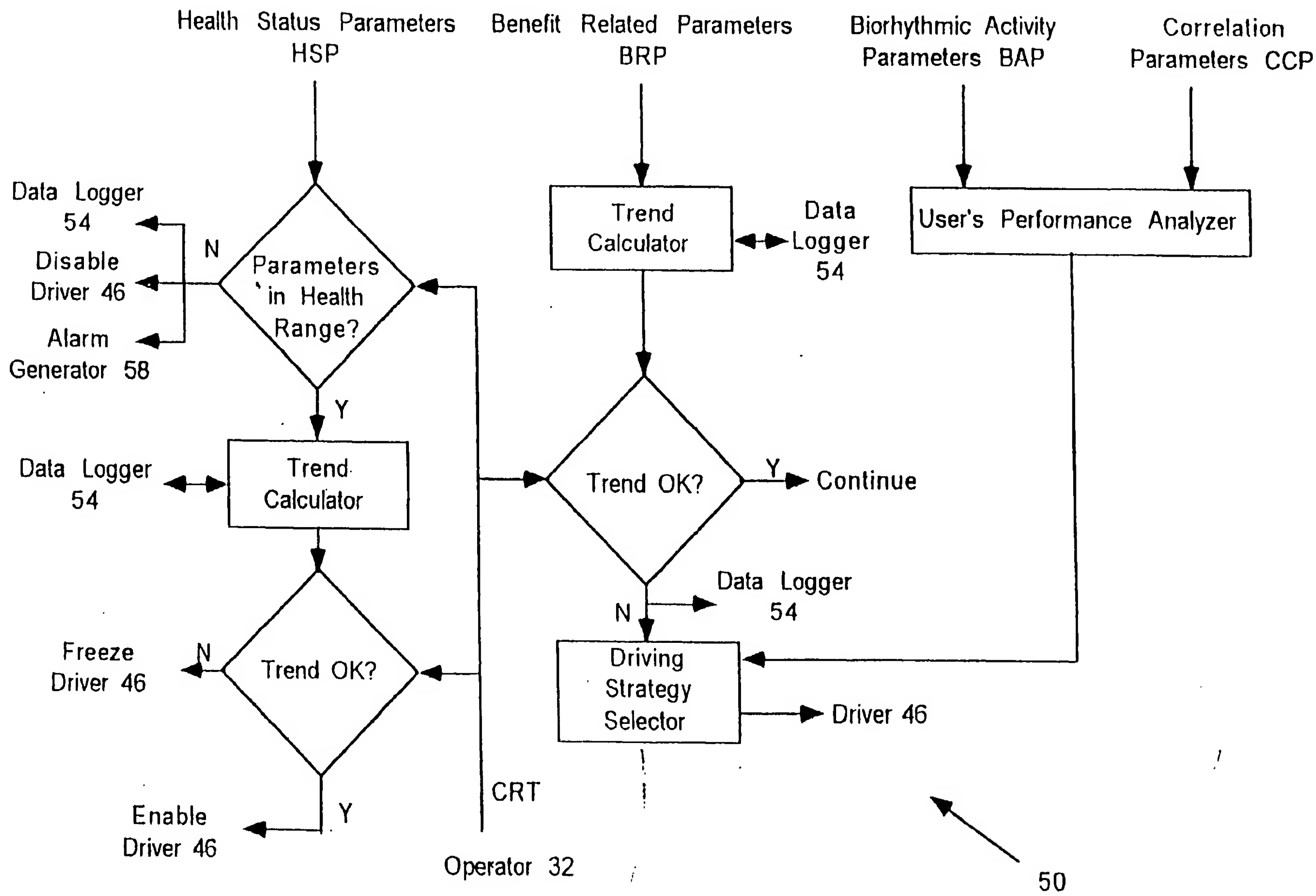


FIG. 4

InterCure Ltd.

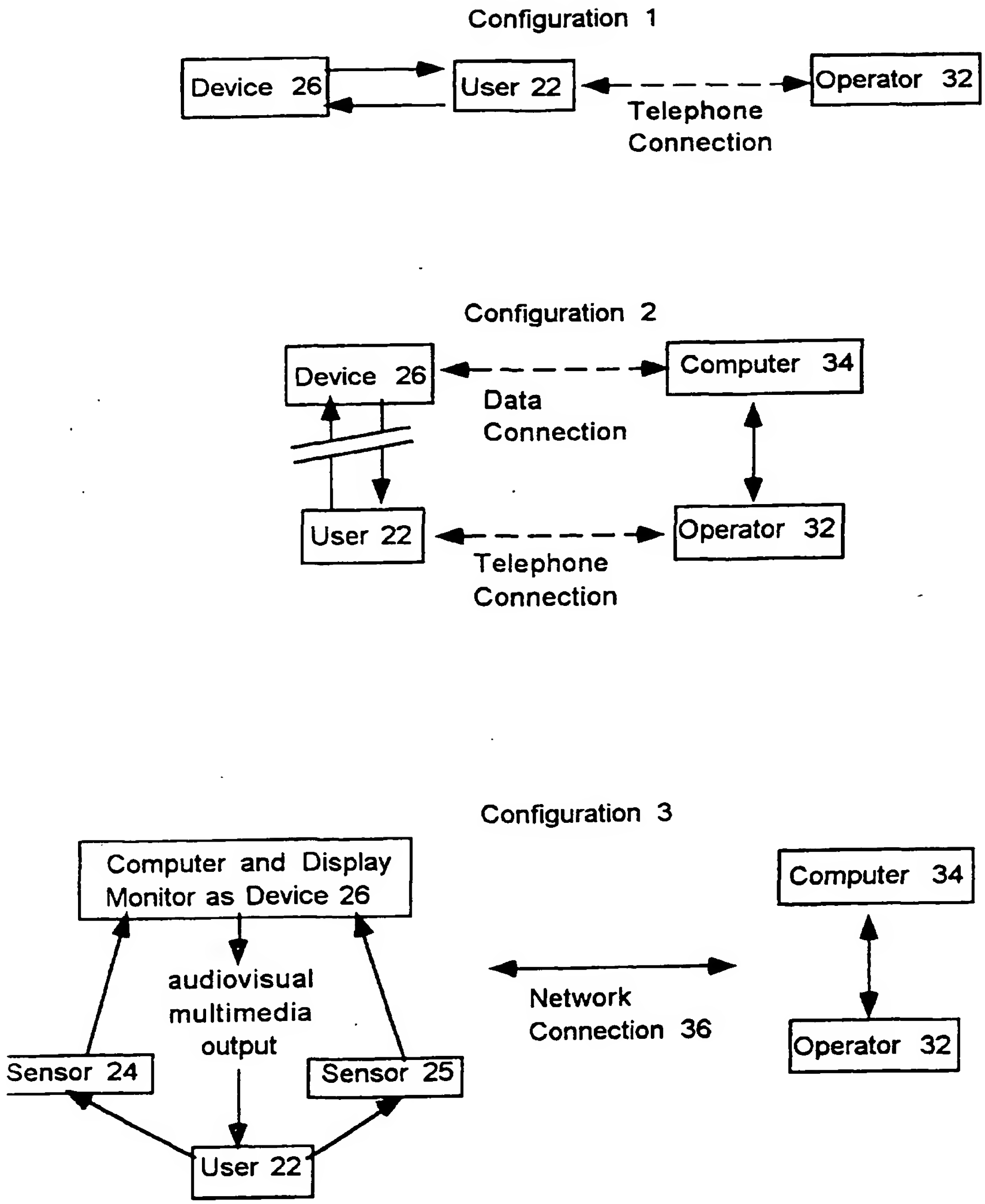

Configuration 1
Device 26
User 22
Operator 32
Telephone Connection
Configuration 2
Device 26
Computer 34
Data Connection
User 22
Operator 32
Telephone Connection
Configuration 3
Computer and Display Monitor as Device 26
audiovisual multimedia output
Sensor 24
Sensor 25
User 22
Network Connection 36
Computer 34
Operator 32

Fig. 5

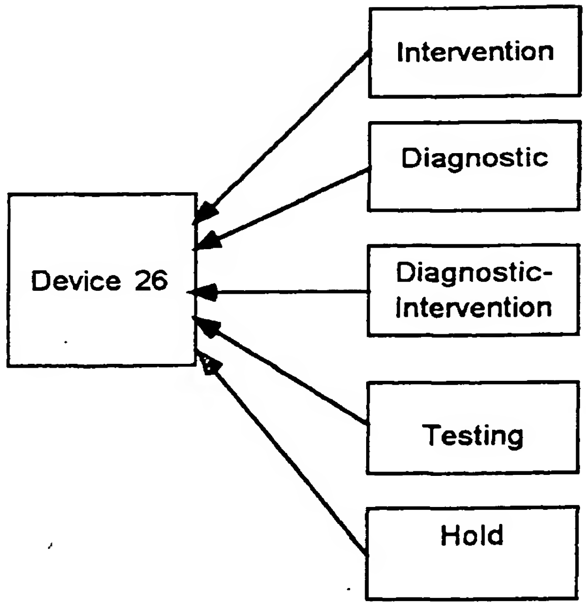

Intervention
Diagnostic
Device 26
Diagnostic-
Intervention
Testing
Hold

Fig. 6

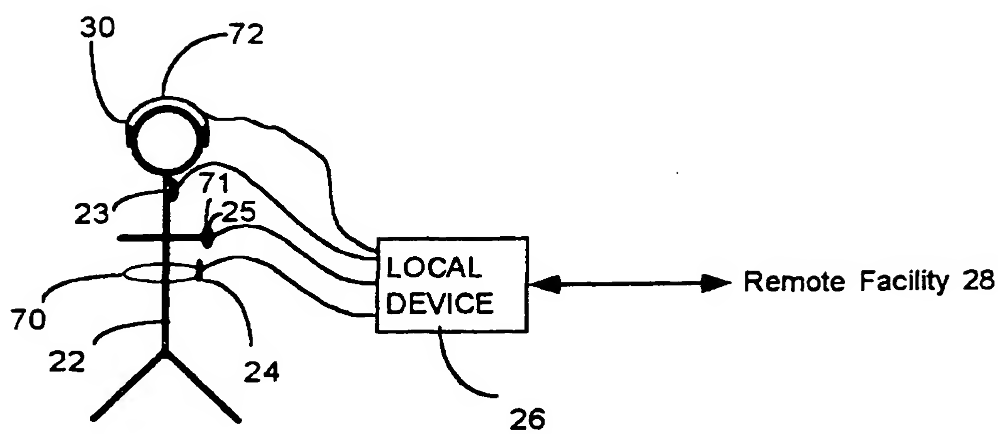
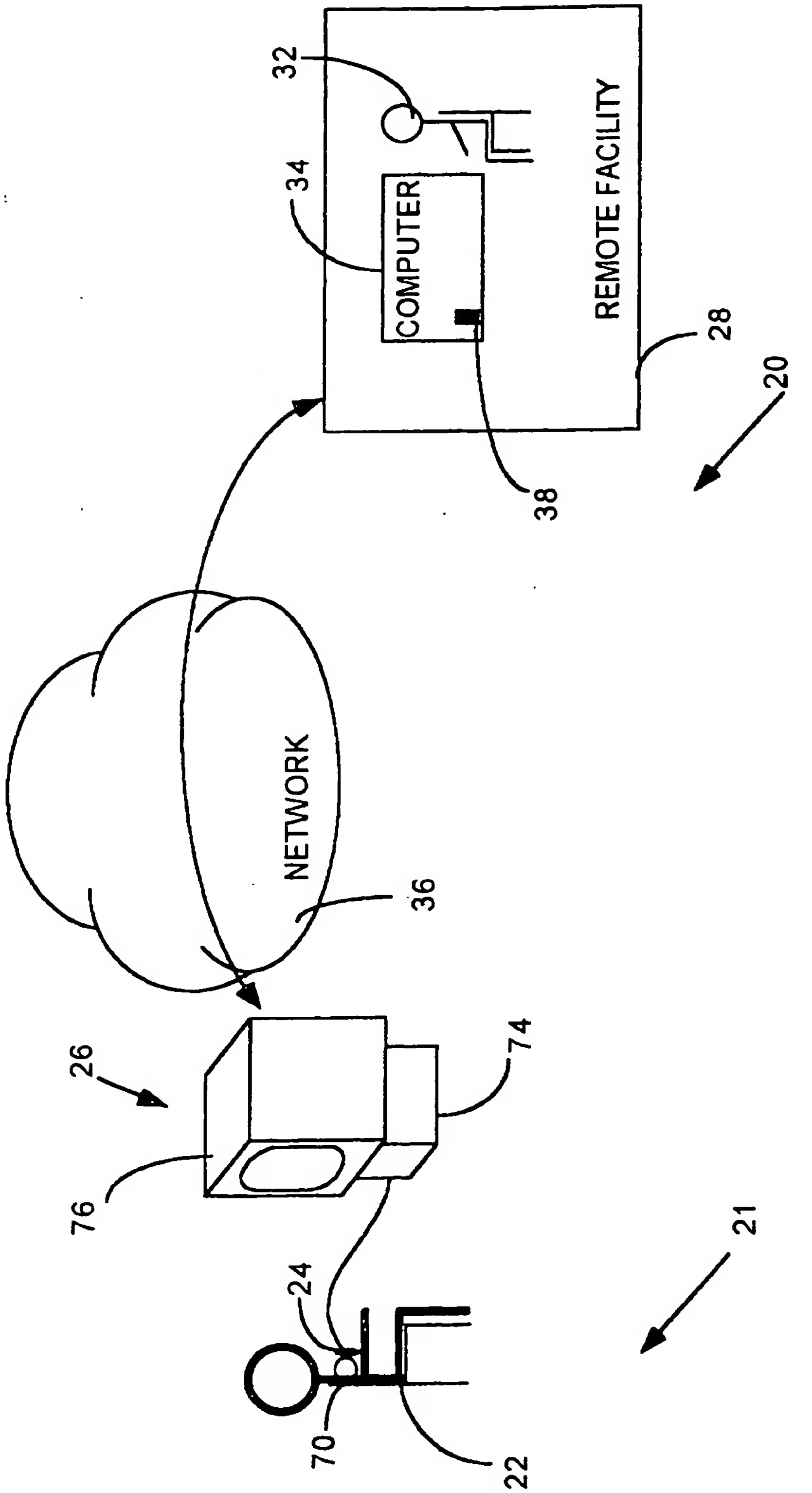

30
72
71
23
25
70
22
24
LOCAL
DEVICE
26
Remote Facility 28

Fig. 7



COMPUTER
REMOTE FACILITY
NETWORK
20
21
22
24
26
28
32
34
36
38
70
74
76

FIG. 9

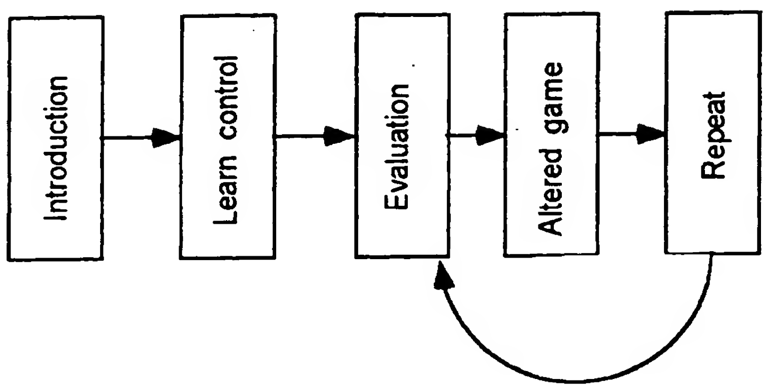

Introduction
Learn control
Evaluation
Altered game
Repeat

Fig. 10

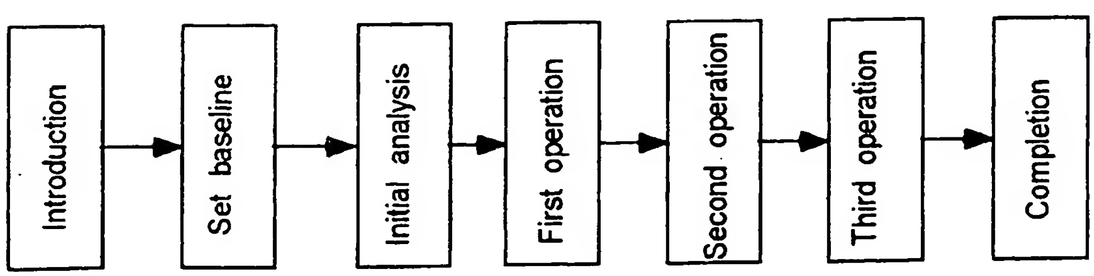

Introduction
Set baseline
Initial analysis
First operation
Second operation
Third operation
Completion

Fig. 8

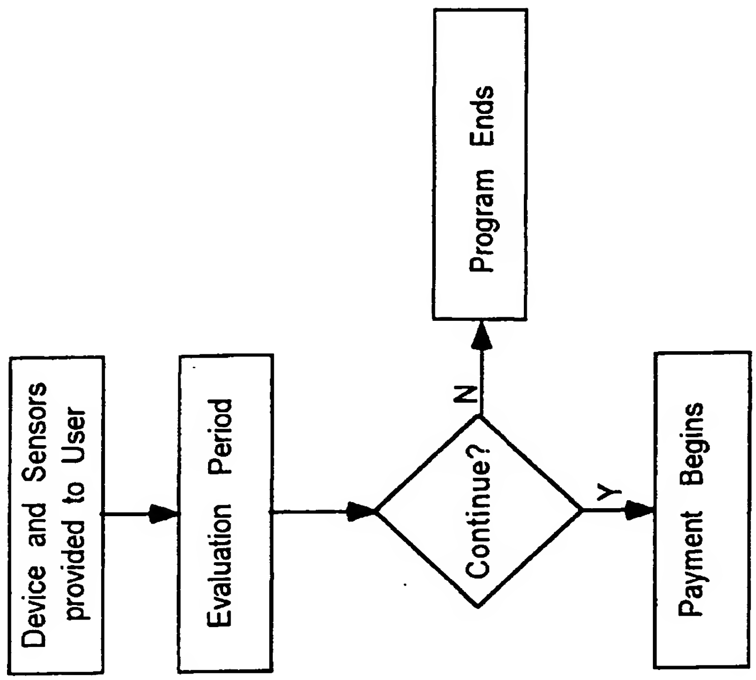

Device and Sensors provided to User
Evaluation Period
Continue?
N
Program Ends
Y
Payment Begins

Fig. 12

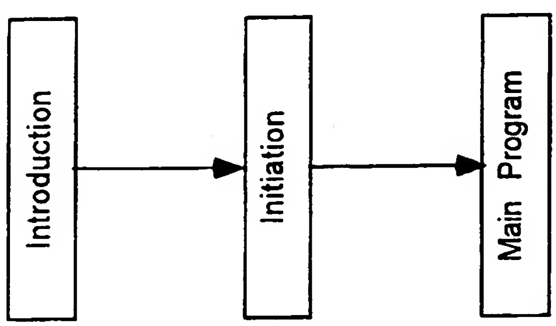

Introduction
Initiation
Main Program

Fig. 11